



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,301	06/25/2003	Phillip Bowler	CV0317 NP	3224

26079 7590 06/22/2006

BRISTOL-MYERS SQUIBB COMPANY
100 HEADQUARTERS PARK DRIVE
SKILLMAN, NJ 08558

EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,301	BOWLER ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/20/03; 12/04/03; 1/20/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The receipt is acknowledges of applicants' preliminary amendment filed 06/25/2005, IDS filed 08/20/2003, IDS filed 12/04/2003, and IDS filed 01/20/2004.

Claims 1-6 have been canceled and claims 7-16 have been added by the preliminary amendment.

Claims 7-16 are pending and included in the prosecution.

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a).
"Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(f) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37
CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A
"Sequence Listing" is required on paper if the application discloses a
nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if
the required "Sequence Listing" is not submitted as an electronic
document on compact disc).

2. The lengthy specification has not been checked to the extent necessary to
determine the presence of all possible minor errors. Applicant's cooperation is
requested in correcting any errors of which applicant may become aware in the
specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that
form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed
publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public
use or on sale in this country, more than one year prior to the date of application for patent in the United
States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by
another filed in the United States before the invention by the applicant for patent or (2) a patent
granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 1615

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7 and 8 are directed to wound dressing comprising anionic, amphoteric or hydrophilic polymer and silver. The expression “for the prevention” is not given patentable weight as it is directed to the intended use of the dressing.

4. Claims 7-11, and 13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/024839 ('839).

WO '839 discloses silver containing antimicrobial hydrophilic material for stabilizing silver comprises matrix comprising polysaccharide incorporating silver (abstract; page 9, lines 16-18). The reference disclosed wound healing and treatment devices (page 9, lines 13-15). The matrix can be in the form of fibers or films (page 10, lines 31-33). The hydrophilic material can be polyacrylate, polyacrylamide, polyvinyl pyrrolidone (PVP), polyurethanes or polysaccharides (page 11, lines 13-18; page 16, lines 10-20). The matrices deliver active agent, preferably silver, to the wound site including silver ions (page 15, lines 19-22, 27-28). Inclusion of silver in the polymer matrix prevents discoloration and enhances antimicrobial activity (page 20, lines 14-15, 22-32; page 21, lines 19-39; page 24, lines 30-39). The amount of silver in the dressing is calculated to be 0.002 to 3.1% (page 22, lines 23-30). Prevention of staining of the underlying tissue is an inherent property of the wound dressing disclosed by WO '839.

5. Claims 7-11, and 13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 02/43743 ('743).

WO '743 discloses photo stable wound dressing comprise hydrophilic, amphoteric or anionic polymer and silver to prevent discoloration of the dressing (abstract; page 1, lines 20-23; page 3, lines 24-30). The polymers include polysaccharide and modified polysaccharides, PVP, polyvinyl alcohol (PVA), polyurethanes, polyacrylates, polyacrylamides, collagen, gelatin or mixtures thereof (page 5, lines 11-15). The amount of silver in the polymer material is between 0.1 to 20% (page 6, lines 5-7). The polymer material can be in the form of fibers (page 5, line 4).). Silver is released from the wound dressing upon rehydration, i.e. contacting the wound exudates (page 8, lines 3-4). Prevention of staining of the underlying tissue is an inherent property of the wound dressing disclosed by WO '743 because silver is photo-stabilized.

6. Claims 7-11, and 13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 02/078755 ('755).

WO '755 discloses wound dressing comprising silver and being capable of releasing antimicrobial silver ions to the wound (abstract; page 14, table 2). The dressing comprises adhesive matrix comprising the silver compound (page 3, last full paragraph). The matrix is polyurethane polymer, inherently hydrophilic, and the amount of silver compound in the dressing is calculated to be about 10% (page 12, example 1). Prevention of staining of the underlying tissue is an inherent property of the wound dressing disclosed by WO '755.

Art Unit: 1615

7. Claims 7-11 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by the article by Nathan et al.

Nathan et al. disclosed wound dressing comprising matrix comprising silver and acrylate polymer (abstract). The amount of silver compound in the dressing between 0.003 to 1.0% (page 1016, left column, first paragraph). Prevention of staining and release of ionic silver are inherent properties of the wound dressing disclosed by Nathan et al.

8. Claims 7-11 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 361 722 ('722).

EP '722 disclosed wound dressing comprises matrix of polyacrylate and silver compound in an amount 0.5 to 3.0% (abstract; page 3, lines 29, 43, 67-68; example 1). Prevention of staining and release of ionic silver are inherent properties of the wound dressing disclosed by EP '722

9. Claims 7-10, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/33632 ('632).

WO '632 disclosed wound dressing comprising alginate powder and silver compound (page 12, lines 10-36). Prevention of staining and release of ionic silver are inherent properties of the wound dressing disclosed by WO '632.

Art Unit: 1615

10. Claims 7-11 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/09173 ('173).

WO '173 disclosed wound dressing comprises hydrophilic polymer and silver compound to prevent discoloration of the dressing (abstract; page 7, line 15). The hydrophilic polymers include polysaccharide, PVP, polyurethanes, polyacrylates, and collagen (page 6, lines 6-10, 13; page 7, lines 1-3). The amount of silver in the polymer material preferably is between 0.5 to 5% (page 7, lines 510-12). The polymer material can be in the form of powder (page 8, line 5). Silver is released from the wound dressing upon rehydration, i.e. contacting the wound exudates (page 8, lines 3-4). Prevention of staining of the underlying tissue is an inherent property of the wound dressing disclosed by WO '173.

11. Claims 7-11 and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,592,888 ('888).

US '888 disclosed wound dressing comprising antimicrobial silver in a polyurethane adhesive and releases the silver ions into the wound bed (abstract; col.3, lines 30-40; col.5, lines 5-9; col.8, lines 1-4). The silver is present in an amount about 1.0% (col.6, lines 53-54). Prevention of staining of the underlying tissue is an inherent property of the wound dressing disclosed by US '888.

12. Claims 7-11, and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0172709 ('709).

US '709 discloses wound dressing comprising silver and being capable of releasing antimicrobial silver ions to the wound. The dressing comprises adhesive matrix comprising the silver compound. The matrix is polyurethane polymer, inherently hydrophilic, and the amount of silver compound in the dressing is calculated to be about 10%. (abstract; paragraphs: 0016-0020, 0029-0032, 0044, 0045, 0060, 0061, 0093). Prevention of staining of the underlying tissue is an inherent property of the wound dressing disclosed by US '709.

13. Claims 7-11, and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,267,782 ('782).

US '782 discloses medical dressing comprising elemental silver and polymer such as polysaccharides, polyurethanes, PVP, collagen and gelatin (abstract; col.3, lines 3-6, 18-20, 32-35; col.5, lines 56-60; col.6, lines 35-67). Silver is released on contact with the body fluid (col.4, lines 10-22). The amount of silver in the dressing is calculated to be between 0.0001 to 2% (col.7, lines 55-59). The dressing can be in the form of fibers (col.9, lines 60-65). Prevention of staining of the underlying tissue is an inherent property of the wound dressing disclosed by US '782.

14. Claims 7-9 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,333,093 ('093).

US '093 discloses wound dressing comprising silver compound and polyurethane polymer and the dressing releases silver ions sufficient to provide antimicrobial effect

Art Unit: 1615

(abstract; col.2, lines 52-61; col.3, lines 5-10; col.4, lines 40-43; col.5, lines 37, 40; col.12, lines 25-30, 44). The dressing eliminates staining from silver leaving patients and relatives less shocked by the discoloration and provides sustained release of silver (col.14, lines 65-67; col.15, lines 1-2, 6-10)

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1615

17. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of WO '839, WO, 743, WO 755, Nathan et al., EP '722, WO '173, US '888, US '782 or US '093.

The teachings of the references are discussed under U.S.C. 102 rejection above. However, the references do not teach the amount of release of ionic silver into water.

The references disclose the release of ionic silver into the wound, and it is expected that the matrix disclosed by any of the references made of the same material and comprises the same amount of silver as instantly claimed will release the same amount of silver into the wound.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprising hydrophilic polymer matrix incorporating silver as disclosed by any of the references, with reasonable expectation of having release of silver ions from the matrix to the wound in an amount less than 1 ppm since silver is incorporated in the same amount in the same hydrophilic polymer matrices.

18. Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of WO '632 or US '093.

The teachings of WO '632 and US '093 are discussed under U.S.C. 102 rejection above. However, WO '632 and US '093 do not each the exact amount of silver in the dressing. The amounts do not impart patentability to the claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

Art Unit: 1615

the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

19. Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '093 in view of US '782.

The teachings of the references are discussed above.

However, US '093 does not teach the dressing in the form of fiber, powder or within a matrix of an adhesive as claimed in claims 10 and 14.

US '782 teaches the inclusion of metal in the fibers prior to forming the fabric provides higher surface area per weight of elemental silver (col.9, lines 60-64).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprising hydrophilic polyurethane and silver as disclosed by US '093, and provide the dressing in the form of fibers as disclosed by US '093 motivated by the teaching of US '782 that fibers provides higher surface area per weight of elemental silver, with reasonable expectation of having fiber wound dressing comprising high surface area including silver to provide the maximum antimicrobial effect to the contacted wound.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER